Application No.:	10/729,830
Applicant:	Von Der Mulbe, *et al.*
Filed:	December 5, 2003
Title:	PHARMACEUTICAL COMPOSITION CONTAINING A STABILISED MRNA OPTIMISED FOR TRANSLATION IN ITS CODING REGIONS
Art Unit:	1636
Confirmation No.:	8653
Examiner:	Dunston, Jennifer Ann
Docket No.:	075067-0501 (CRVC-001 US)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Considered
4/10/2007
GD

DECLARATION OF DR. INGMAR HOERR UNDER 37 C.F.R. § 1.132

Dear Sir:

I, Ingmar Hoerr, hereby declare that:

1. I am one of the inventors of the invention disclosed in the above-identified patent application ("the '830 application"), and, thus, I am familiar with the application and the invention claimed therein.

2. I hold a doctorate from the University of Tuebingen, Germany. My doctorate research was on RNA vaccines. I have several years of experience and active scientific research activity, and numerous publications in the field of mRNA and, more specifically, stabilized mRNA. A *curriculum vitae* is attached herewith as **Exhibit A**.

3. I am a founder of and I presently hold the position of Chief Executive Officer of CureVac GmbH in Tuebingen, Germany, the Assignee of the '830 application.

4. I have reviewed and understand the Office Action mailed April 17, 2006. I am submitting this declaration to respond to some of the Examiner's comments regarding the .

5. The Examiner seems to be concerned that the patent application does not provide working examples showing therapeutic effects. For example, the April 17, 2006 Office Action states: "While the specification and working examples teach how to make a modified mRNA that meets the structural characteristics of the claimed invention, the specification does not teach how to use the pharmaceutical compositions for any therapy. No working examples that demonstrate a therapeutic outcome are provided." Office Action at pages 7-8. With respect to the state and predictability of the art, the Examiner stated that: "The use of RNA for vaccination is unpredictable in that the process depends upon cell-specific and tissue-specific efficient transfer of the nucleic acid... Furthermore, the success of nucleic acid vaccination is unpredictable with regard to obtaining a prophylactic or therapeutic effect..." Office Action at pages 8-9.

6. A series of studies are described in the attached **Exhibit B** that are believe to address the Examiner's concerns. The studies were conducted using compositions of the claimed invention (*i.e.*, compositions comprising at least one modified mRNA that encodes at least one biologically active or antigenic polypeptide and a pharmaceutically compatible carrier